A non randomised open pilot study in palliative care: investigating the feasibility and preliminary effectiveness of an exercise program in palliative cancer patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON34881

Source
ToetsingOnline

Brief title
Active rehabilitation in palliative cancer care

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
advanced kanker

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: advanced cancer, exercise, physical functioning, Quality Of Life

Outcome measures

Primary outcome

• Feasibility in execution of an exercise program in this population:

o Experienced problems (of participants and PT)

o Participant experiences

o Participants believes (of movement and the training

sessions)

o Adverse events (AE)

o Adherence

o Obtainment of individual and/or general goals (4)

Secondary outcome

• (Physical) limitations in physical functioning

• QOL

• Level of symptoms:

o pain

o fatigue

o anxiety/depression

• Physical fitness level:

o muscle force

o functional capacity, by walking distance

• Body composition (body fat percentage)

• Subjective experienced intensity of exercise

Study description

Background summary

Often, cancer patients suffer from severe symptoms as fatigue, decreased muscle strength and physical fitness, which results in a decreased level of physical activity. This can have a major impact on the patients Activities of Daily Living (ADL) and participation in social life. Also, the decreased level of physical activity maintains the decreased level of physical fitness, so patients are in a negative vicious circle. For curative cancer patients there is scientific evidence that exercise can have a positive impact on these symptoms and can break this negative vicious circle. Studies specifically dealing with physical exercise among palliative patients or non-curative treated patients with persistence cancer and/or metastasis and/or relapse are few and have methodological limitations, so scientific evidence for physical exercise in this population is poor. Although these studies show promising results that exercise, aerobic as well as resistance training, may serve as additional palliative treatment to improve well-being and physical capacity. Yet more trials are needed to confirm these results.

Study objective

The aim of this study is to determine the feasibility and preliminary effectiveness of an exercise program in cancer patients with metastasis and/or relapse, and to explore other limitations than physical fitness and their effect on physical functioning.

Study design

A non randomised open pilot study.

Intervention

All the included subjects will receive a six weeks during physical exercise program. This program consist of aerobic exercise combined with resistance exercise in one training session. Subjects will receive two training sessions a week for two hours in groups of 3-5 persons. Training sessions will be supervised by a physical therapist. Subjects are also advised to exercise

aerobically independent on the non-trainings days following the graded activity principle.
The trainingsprogram will be adjusted to the subjects individual physical fitness following the graded activity principle. Graded activity comprises that the focus in the trainingsprogram will be on succes experiences and that negative experiences are avoided as much as possible. Goals will be set in a specific timeline, two individual goals by the subject and two general goals by the supervising physical therapist. Baseline training will be set on a non-threatening level for the subject. Training intensity will be gradually build up during the training program. This will be achieved by scoring the subjective training intensity of the subject at the end of each training with the Borg-scale, on which the following training will be adjusted. Restperiods will be gradually declined during the training program adjusted to the recovery of the subject.

Each training session comprises:
- warming-up (10 min.)
- aerobic training (30 min.)
- circuit training with resistance exercise (25 min.)
- cooling-down (10 min.).

Warming-up comprises aerobic exercises executed in standing or seated position. Aerobic exercise comprises bicycling on a hometrainer, if this is not possible walking on a treadmill is also allowed. Intensity is set on >= 60% HRmax. Arobic exercise will comprise interval training of 4x4 minutes on 80-90% of HRpeak alternate with 3 minutes of activie rest on 50-70% of HRpeak. Also there is a warming-up in the aerobic training of 10 minutes and a cooling-down of 5 minutes, both executed on 60-70% of HRpeak. Resistance exercise will be executed in 3 series of 8-10 exercises with 8-12 repetitions on 60-80% of 1 repetition maximum (1RM). This training aims on the greater muscle groups which are important in ADL-activities, like the shoulder, arm, back, hip and leg muscles. Every station of resistance exercise has possibilities for individual adjustments.

Study burden and risks

Burden:
When the subject is informed and accepts inclusion, a intake will follow with the physical therapist. De physical therapist will perform a medical history and a physical examination with additional (physical) tests (anthropometric measures, 6 min. walking test and muscle force measures with HHD and HGD). Subjects will be asked to fill in questionnaires (RAND-36, EORTC QLQ-C30, ESAS, CIS, HADS and Last-meter) and a Physical Activity Diary (PAD, one a day), where they also score the intensity of the physical activities with a Borg-scale and pain (NRS).
In week 3 and 6 these measuremnets will be repeated. The questionnaires will be filled in by the subjects and the physical therapist will repeat the physical measurements. Anthropometric measurements and medical history will only be

repeated in week 6.

Risks:
The study design is chosen with hardly any risks for the subjects. During the training sessions adequate safety measures are build in, like monitoring the Heart Rate and exercises in small groups of 3-5 persons so there is sufficient individual supervision. Also, the intervention is adjusted to the subjects individual physical fitness level following the graded activity principle, whit that the frail population is taken into account. Subjects having clinical relevant comorbidity are excluded from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age 18+
• Persistent cancer and/or metastasis and/or relapse
• Minimum of physical activity level of walking 6 minutes successively
• Signed informed consent
• Life expectancy of minimum three months
• Living in region Nijmegen-Den Bosch-Uden or the ability to travel to the physical therapy practices where the training sessions are executed (physical ability as well as logistic ability)
• With the desire to increase physical activity

Exclusion criteria

• Treatment for arrhythmia or myocardial infarction within last 3 months
• Subjects in need of terminal care
• Subjects with clinical relevant cognitive and/or emotional restrictions that prohibits execution of the study according to the doctor
• Subjects who do not speak the Dutch language, and/or are not able to fill in the questionnaires and/or are not able to understand verbal instructions
• Subjects who are not able to come to the physical therapy practice for the training sessions
• Subjects who have already participated in a rehabilitation program within the last 3 months

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	30

Type:	Actual

Ethics review

Approved WMO Date:	03-02-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30080.091.09